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Drug Enforcement Administration

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Chemical Handler's Manual

A Guide to Chemical Control Regulations

Message from the Administrator

The Drug Enforcement Administration (DEA) is pleased to provide the ***Chemical Handler's Manual*** to assist you in understanding the provisions of the Chemical Diversion and Trafficking Act of 1988, the Domestic Chemical Diversion Control Act of 1993, the Comprehensive Methamphetamine Control Act of 1996, and their implementing regulations. These Acts amended the Controlled Substances Act of 1970 (CSA). This manual will answer questions you may have concerning your responsibilities under these Acts and provide you with guidance in complying with their regulations.

The proliferation of illicit drugs in the United States is an issue of national importance. The chemical control acts provide the Drug Enforcement Administration with tools to reduce illicit drug production by denying drug traffickers the chemicals they need to produce illicit drugs. When transactions by chemical handlers involving diversion to illicit channels are revealed, these transactions invariably damage the reputation of the companies involved. Your development of a program to prevent diversion of your products by adherence to the law, together with your voluntary cooperation to achieve its objectives, preserves your good reputation and constitutes a powerful resource for protecting the health and safety of our nation.

Sincerely,

Donnie R. Marshall
Administrator
Drug Enforcement Administration

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Application of Federal and State Law

Nothing in this manual shall be construed as authorizing or permitting any person to commit any act which is prohibited under other federal laws or obligations under international treaties, conventions, or protocols or state laws. The policy statements and other information in this guide are for the purpose of explaining the Controlled Substances Act (CSA) and its implementing regulations and should not be construed as permitting any person to commit any act prohibited by federal or state law.

The chemical control program is relatively new and steadily evolving. Regulated persons should check periodically for new provisions. New and proposed rules can be found in the Federal Register, or online (http://www.access.gpo.gov/nara/index.html), or by calling 1-888-293-6498. Printed copies of the complete regulations implementing the CSA (Title 21, Chapter II, Code of Federal Regulations (21 CFR), Part 1300 to end), may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

The Drug Enforcement Administration

The Drug Enforcement Administration is the federal law enforcement agency charged with the responsibility for combating illicit drug manufacture and distribution, as well as the diversion of licitly produced drugs and chemicals. The DEA was established on July 1, 1973, by Presidential Reorganization Plan No. 2 of 1973. It resulted from the merger of the Bureau of Narcotics and Dangerous Drugs, the Office of Drug Abuse Law Enforcement, the Office of National Narcotics Intelligence, elements of the Bureau of Customs which had drug investigative responsibilities, and those functions of the Office of Science and Technology which were drug enforcement related. The Administration was established to control more effectively narcotic and dangerous drug abuse through enforcement and prevention. In carrying out this mission, the DEA cooperates with other federal agencies, foreign, State, and local governments, private industry, and other organizations.

Origins of the Laws and Regulations

Most illicitly produced drugs result from processes which require chemicals. Drug traffickers depend on access to a variety of chemicals in all parts of the world.

DEA embarked upon a broad chemical control program in 1989 that was based on the Chemical Diversion and Trafficking Act (CDTA) of 1988. At that time, U.S. companies were the main source for 20,000 metric tons of various chemicals used annually to manufacture cocaine in the Andean countries of South America. Among the principal chemicals used by the cocaine manufacturers are acetone, methyl ethyl ketone, ethyl ether, potassium permanganate, hydrochloric acid, methyl isobutyl ketone, and sulfuric acid. The quantity of these chemicals shipped to South America from the United States declined greatly after the CDTA went into effect.

The CDTA was also effective in reducing the supply of illicit methamphetamine. The number of clandestine laboratories seized in the first three years following the law's implementation reversed the trend of the previous three decades and declined by 61 percent. In addition, injuries attributed to illicitly manufactured controlled substances that were reported through the Drug Abuse Warning Network declined by almost 60 percent between 1989 and 1992.

Maintaining this success requires continuous effort to thwart traffickers' never-ending search for new methods of diversion. This is illustrated by more recent changes in the patterns of diversion:

– When the quantity of U.S. chemicals shipped to cocaine manufacturing areas declined, chemical suppliers from other parts of the world emerged as new sources of supply. The U.S. government then undertook an aggressive international campaign to educate and elicit the support of other nations in establishing chemical controls. Today, there is a broad level of international agreement regarding the actions that must be taken to achieve chemical control. Many nations have passed laws to prevent diversion of chemicals.

– As a result of government controls, ephedrine and other chemicals used to manufacture methamphetamine became more difficult to divert. Traffickers then began using over-the-counter capsules and tablets that contained these ingredients. As chemicals rendered into legitimate medicines purportedly for the commercial market, these products were exempted from the CDTA requirements. The Domestic Chemical Diversion Control Act of 1993 (DCDCA) closed this loophole and required DEA registration for all manufacturers, distributors, importers and exporters of List I chemicals. It also established record keeping and reporting requirements for transactions in single-entity ephedrine products.

– When single-entity ephedrine products became regulated, drug traffickers turned to pseudoephedrine. This was addressed by the Comprehensive Methamphetamine Control Act of 1996 (MCA) which expanded regulatory control of lawfully marketed drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine.*

Traffickers continue to look for loopholes in the laws and for new methods of illicit manufacture. The government continually monitors the situation. When new patterns of abuse and diversion are identified, the government responds with corrective action, striking a balance which allows the supply of chemicals for legitimate commerce while limiting the availability of chemicals for illicit drug production. DEA recognizes the importance of educating industry on the targets and tactics of the illegal drug trade and partnering with industry on preventing diversion as the best overall approach to defeating drug traffickers.

*Due to concerns regarding harmful side effects that phenylpropanolamine (PPA) can have, the Food and Drug Administration initiated action in November 2000 to remove PPA from the market. These changes in the status of PPA are not yet reflected in the regulations nor in this manual.

Principal Provisions of the Chemical Diversion Control Laws and Regulations

The Chemical Diversion and Trafficking Act of 1988 (CDTA), the Domestic Chemical Diversion Control Act of 1993 (DCDCA), and the Comprehensive Methamphetamine Control Act of 1996 (MCA) are the legislative acts which are the foundation of the government's program to prevent chemical diversion. These laws and the implementing regulations seek to strike a balance between allowing the chemical handler to pursue legitimate business while limiting the availability of chemicals for illicit drug production.

The laws and regulations require regulated persons (manufacturers, distributors, importers, and exporters of listed chemicals) to implement measures which prevent diversion by:

- obtaining proof of identity from their customers (21 U.S.C. § 830 (a)(3) and 21 CFR §1310.07)
- maintaining retrievable receipt and distribution records (21 U.S.C. § 830 (a) and 21 CFR Part 1310), and
- reporting to the Drug Enforcement Administration (DEA) any suspicious orders[1] (21 U.S.C. § 830 (b)(1) and 21 CFR §1310.05 (a)(1)).

Manufacturers who distribute or export, distributors, importers, and exporters of List I chemicals are also required to:

- register with DEA (21 U.S.C. § 822 (a)(1) and 21 CFR §1309.21), and
- provide controls and procedures to guard against theft and diversion. (21 U.S.C. § 823 (h) and 21 CFR §1309.71-73).

[1]Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law.

Regulated persons (importers, exporters, brokers and traders in international transactions and transshippers) are required to notify DEA at least 15 days prior to the date of the transaction (21 U.S.C. § 971 (a) and 21 CFR Part 1313). The notification may be provided to DEA on or before the date of importation or exportation under certain conditions. The conditions are specified in the sections titled "Waiver of 15-Day Advance Notification Requirement" and "Criteria for Waiver of Advance Notification Requirement."

Some manufacturers of List I and List II chemicals are required to report annual production data (21 U.S.C. § 830 (b)(2) and 21 CFR §1310.05 (d)).

Inspection Authority

21 U.S.C. § 822 (f) and 21 CFR § 1316.03

DEA has the authority to enter and conduct an inspection of places, including factories, warehouses, or other establishments and conveyances, where persons registered under the CSA, or exempted from registration under the CSA, or regulated persons may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals or where records relating to those activities are maintained. Inspectors are authorized to:

- enter controlled premises and conduct administrative inspections for the purpose of inspecting, copying, and verifying the correctness of records, reports, or other required documents;
- inspect within reasonable limits and to a reasonable manner equipment, finished and unfinished controlled substances, listed chemicals, and related materials and containers;
- make a physical inventory of all controlled substances and listed chemicals on-hand at the premises;
- collect samples of controlled substances or listed chemicals.

Suspension of Shipments

21 U.S.C. § 971 (c) and 21 CFR § 1313.41

DEA has the authority to suspend shipments of a listed chemical for import or export which are not destined for legitimate medical, scientific, or commercial use. DEA may suspend any importation or exportation of a listed chemical based on evidence that the chemical may be diverted for use in the clandestine manufacture of a controlled substance. When a shipment is suspended, the Administration will

issue a suspension notice to the regulated person explaining the circumstances of the suspension.

The regulated person to whom the suspension order applies may request an administrative hearing under the Administrative Procedure Act (5 U.S.C. §551 - 559) to determine the issues involving the suspension of shipment (see 21 CFR §1313.51-1313.57). A request for a hearing must be made within 30 days after receipt of shipment suspension notice.

Active Voluntary Compliance

The CDTA, the DCDCA and the MCA imposed reporting requirements on the chemical industry. However, the involvement of private industry and the public should not be limited to the laws enacted by Congress. The vast majority of industry recognizes and supports the idea that the responsibilities of the chemical industry extend beyond the letter of the law to actively supporting efforts to stop the flood of clandestinely produced drugs which plague our nation. Industry's voluntary support constitutes a powerful resource for protecting the health and safety of our nation. We urge each firm to be vigilant and to become a partner with DEA in combating the diversion of chemicals to illegal drug production.

Definitions

Complete definitions appear in 21 CFR Part 1300 and 21 U.S.C. § 802.

Broker and Trader (in an international transaction)
A broker and trader is any individual, corporation, corporate division, partnership, association, or other legal entity which assists in arranging an international transaction in a listed chemical by

- negotiating contracts;
- serving as an agent or intermediary; or
- fulfilling a formal obligation to complete the transaction by bringing together a buyer and seller, a buyer and transporter, or a seller and transporter, or by receiving any form of compensation for so doing.

Chemical Exporter
A *chemical exporter* is a regulated person who has the power and responsibility for controlling the sending of a listed chemical out of the United States.

Chemical Importer
A *chemical importer* is a regulated person who has the power and responsibility for controlling the bringing in or introduction of a listed chemical into the United States.

Chemical Mixture
A *chemical mixture* is a combination of two or more chemical substances, at least one of which is not a listed chemical. Specific mixtures may be exempted by DEA. Contact DEA for up-to-date information.

Established Business Relationship with a Foreign Customer
An *established business relationship with a foreign customer* means that the regulated person has exported a listed chemical at least once within the past six months, or twice within the past twelve months to a foreign manufacturer, distributor, or end user of the chemical that has an established business in the foreign country with a fixed street address. A person or business which functions as a broker or intermediary is not a customer for purposes of this definition. The term also means that the regulated person has provided DEA with specified information in accordance with the waiver of 15-day advance notice requirements. DEA can disqualify the foreign

customer for waiver of the advance notification requirement. Written explanation of the reasons will be provided. The regulated person is entitled to a hearing within 45 days after the written request.

Established Record as an Importer

Established record as an importer means that the regulated person has imported a listed chemical at least once within the past six months, or twice within the past 12 months from a foreign supplier. The term also means that the regulated person has provided DEA with the following information, in accordance with the waiver of the 15-day advance notice requirements:

(a) the name, DEA registration number (where applicable), street address, telephone number, telex number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and

(b) the frequency and number of transactions occurring during the preceding 12-month period.

DEA can disqualify the importer for waiver of the advance notification requirement. Written explanation of the reasons will be provided. The regulated person is entitled to a hearing within 45 days after the written request.

International Transaction

International transaction is a transaction arranged by a broker or trader located in the United States involving the shipment of a listed chemical across an international border (other than a U. S. border).

Listed Chemical

Listed chemical is any List I chemical or List II chemical. A listing appears in Appendix A.

List I Chemical

List I chemical is a chemical that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the CSA and is designated a List I chemical by the DEA Administrator or Congress. Chemicals in List I generally are precursors and have been determined by DEA to require a greater level of control than other listed chemicals. Anthranilic acid, ergotamine, piperidine, and drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine are examples of List I chemicals.

List II Chemical

List II chemical is a chemical, other than a List I chemical, that, in addition to legitimate uses, is used in manufacturing a controlled

substance in violation of the CSA and is designated a List II chemical by the DEA Administrator or Congress. Chemicals in List II are generally reagents and solvents.

Readily Retrievable

Readily retrievable means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner made visually identifiable apart from other items appearing on the record.

Registrant

Registrant is a person who distributes, imports, exports, or manufactures for distribution or export any List I chemical and who has been granted a Certificate of Registration by the Administrator of DEA to manufacture for distribution, distribute, import or export List I chemicals. Also included are certain controlled substances registrants who handle List I chemicals.

Regulated Person

A *regulated person* is any individual, corporation, partnership, association or other legal entity who manufactures, distributes, imports, or exports a listed chemical, or a tableting machine or encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or encapsulating machine.

Regulated Transaction

21 U.S.C. §802 (39) and 21 CFR § 1300.02 (b)(28)

A *regulated transaction* is a distribution, receipt, sale, importation, exportation, or international transaction involving shipment of a threshold amount of a listed chemical (including a cumulative threshold amount for multiple transactions), a tableting machine or an encapsulating machine.

The following transactions are not regulated:

- normal distribution between agents or employees of a single regulated person, and delivery to a common or contract carrier or to or by a warehouseman for storage, unless the carriage or storage is in connection with the distribution, importation or exportation of a listed chemical to a third party.
- any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act **unless**

-- the drug contains ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, or salts of optical isomers; **or**

-- the Administrator has determined that the drug or group of drugs is being diverted; and

-- the quantity of listed chemical equals or exceeds the threshold established for that chemical.

• sales by retail distributors of ordinary over-the-counter pseudoephedrine or phenylpropanolamine products, directly to walk-in customers or in face-to-face transactions, in below-threshold quantities in a single transaction to an individual for legitimate medical use. Ordinary over-the-counter pseudoephedrine or phenylpropanolamine products are non-liquids sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base and packaged in blister packs, each blister containing not more than two dosage units or where the use of blister packs is technically infeasible, packaged in unit dose packets or pouches and for liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or phenylpropanolamine base.

• any transaction in a chemical mixture that the Attorney General has by regulation designated as exempt based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered. Chemical handlers should check the Federal Register for the issuance of a final rule on chemical mixtures and subsequent changes.

• the following transactions have been determined to be exempt:

-- domestic and import transactions of hydrochloric and sulfuric acids but not including anhydrous hydrogen chloride

-- import transactions of anhydrous hydrogen chloride

-- exports, transshipments, and international transactions of hydrochloric and sulfuric acids, **except for exports, transshipments and international transactions to the following countries:**

Argentina	Bolivia	Brazil	Chile	Colombia
Ecuador	French Guiana		Guyana	Panama
Paraguay	Peru	Suriname	Uruguay	Venezuela

-- domestic transactions of methyl isobutyl ketone (MIBK)

-- import transactions of MIBK destined for the United States

-- export transactions, international transactions, and import transactions for transshipment or transfer of MIBK destined for Canada or any country outside of the Western Hemisphere

-- import and export transactions of iodine.

Retail Distributor

(relates only to drug products containing ephedrine, pseudoephedrine and phenylpropanolamine) 21 CFR §1300.02(29)

A *retail distributor* is a grocery store, general merchandise store, drug store, or other merchandise store, or other entity or person whose activities as a distributor relating to drug products containing pseudoephedrine, phenylpropanolamine or ephedrine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. Sale for personal use means the distribution of below-threshold quantities in a single transaction to an individual for legitimate medical use.

The MCA defines retailer as an entity or person whose activities as a distributor of legal drug products containing listed chemicals are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. Distributors who do not meet the retail definition are subject to the requirements for wholesale distributors.

Registration

21 U.S.C. § 822, 823
21 CFR Part 1309

Who Must Register

Every person (unless specifically exempted below) who engages or proposes to engage in any of the following activities is required to register annually with DEA:

- manufacturing a List I chemical for distribution
- distribution of a List I chemical
- importation of a List I chemical
- exportation of a List I chemical

Separate Registration for Independent Activities

21 CFR §1309.22

The following groups of activities are independent of each other and each requires a separate registration:

1. Retail distributing of drug products that contain List I chemicals. Sales of chemicals such as hydriodic acid or methylamine are non-retail distributions.
2. Non-retail distributing of List I chemicals;
3. Importing List I chemicals (note that importers are authorized to distribute those List I chemicals which they have imported); and
4. Exporting List I chemicals.

Separate Registration for Separate Locations

21 CFR § 1309.23

A separate registration is required for each principal place of business where a List I chemical is manufactured for distribution, distributed, imported, or exported.

Exemptions from Registration Requirement

21 CFR § 1309.24-29

Exempt from registration are:

- a manufacturer of a List I chemical who uses the chemical solely for internal consumption without subsequent distribution or exportation.
- a person who imports or exports a drug product containing a List I chemical if that person is registered with DEA to engage in the same activity with a controlled substance. Security, record keeping and reporting requirements apply.
- a person who distributes a drug product containing a List I chemical, if that person is registered with DEA to manufacture, distribute, or dispense controlled substances. Activities with drug products containing List I chemicals should remain consistent with controlled substances activities; e.g., a retail pharmacy registrant should engage in retail sales rather than wholesale distributions of regulated drug products. Security, record keeping and reporting requirements apply. Distribution of List I chemicals requires a separate registration.
- retail distributors of ordinary over-the-counter pseudoephedrine and phenylpropanolamine drug products.
- retail distributors whose activities as distributors of non-ordinary over-the-counter drug products and combination ephedrine drug products are limited exclusively to sales for personal use, either directly to walk-in customers or in face-to-face transactions by direct sales. Sale for personal use is the sale of below-threshold quantities in a single transaction to an individual for legitimate medical use.

Any distributions of single-entity ephedrine are subject to the registration requirement.

Applying for Registration

An application for registration (DEA Form 510), and information regarding current fees and renewal of registration may be obtained by contacting your nearest DEA office or by writing to:

U.S. Department of Justice
DEA, Chemical Registration/ODIA
P.O. Box 2427
Arlington, VA 22202-2427

Security

21 U.S.C. § 823 (h) and
21 CFR § 1309.71

Registrants are required to provide effective controls and procedures to guard against theft and diversion of List I chemicals. Historically, distributors have focused on knowledge of the customer and close attention to sales as a means to control diversion. Registrants recently have experienced significant thefts of drug products and bulk material. These chemicals are highly sought on the illicit market. It is important for legitimate handlers to provide extra safeguards for chemicals in their possession.

Specific attention should be paid to the following areas:

- A List I chemical should be sealed in a container that will reveal any attempts at tampering. If a chemical cannot be stored in such a sealed container, access to the chemical should be controlled through physical means (i.e., locked in a secure place) or through human or electronic monitoring.
- In a retail setting open to the public, single-entity ephedrine products must be stocked behind a counter where only employees have access.
- The registrant should exercise caution in considering the employment of persons who have been convicted of a felony offense relating to controlled substances or listed chemicals. The registrant should assess the risks involved in employing such persons, including the potential for revocation of registration.
- An employee who has knowledge of diversion by a fellow employee has an obligation to report such information to the employer or a responsible representative of the employer. A failure to report such information will be considered in determining future access to areas with List I chemicals. It is the employer's responsibility to inform employees of this policy.
- Some of the factors that registrants should take into account when planning for security include:

1. the quantity of List I chemicals handled,
2. the location of the premises,
3. the type of building construction and the general characteristics of the building,
4. electronic detection and alarm systems,
5. the extent of unsupervised public access to the facility
6. the adequacy of supervision over employees who have access to List I chemicals,

7. procedures for handling guests, maintenance personnel and non-employee service personnel, and
8. adequacy of systems for monitoring receipt, distribution and disposition of List I chemicals.

Any registrant or applicant desiring to determine whether a proposed system of security controls and procedures is adequate for listed chemicals may submit materials and plans regarding the proposed security controls and procedures either to the local Diversion Group Supervisor or to DEA, Chemical Registration Section/ ODIA, PO Box 2427, Arlington, VA 22202-2427.

"Know Your Customer" Policy

It is fundamental for sound operations that handlers take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, identify those transactions conducted by their customers that are suspicious in nature. Regulated persons are encouraged to thoroughly review the Appendices, particularly *E-1, E-2,* and *E-3***.**

Some states have restrictions on distribution practices that are more stringent than the federal rules. The extent of compliance with state law is taken into consideration when civil, administrative, or criminal actions are under consideration.

It is required that any regulated person verify that a customer for List I products possesses a valid DEA registration or is exempted from that requirement.

The granting of a DEA registration signals only a proper application, the establishment of the required records system, and the required security system at the time of the on-site inspection by DEA. The registration is not a confirmation of proper ongoing business practices and does not relieve the chemical handler of the responsibility to evaluate each transaction.

Proof of Identity

21 U.S.C. § 830 (a)(3) and 21 CFR § 1310.07

The CSA requires that a regulated person engaging in a regulated transaction must identify the other party to the transaction. The regulated person must verify the existence and apparent validity of a business entity ordering a listed chemical, tableting or encapsulating machine and maintain customer files. **If the regulated person is unable to establish the identity or legitimacy of a customer, sound practice requires the handler to postpone opening an account with this customer until such information is satisfactorily established.** Regulated persons should maintain customer files which may be reviewed for adequacy by DEA during on-site visits.

For domestic transactions, this may be accomplished at the time the order is placed by having the other party present documents to verify their identity and registration status if a registrant. Verification of documents may be accomplished through the following sources: telephone directory, local credit bureau, local Chamber of Commerce, or the local Better Business Bureau. DEA registration may be verified by DEA. When transacting business with a new representative of a firm, the regulated person must verify the agency status of the representative.

For cash sales or sales to individuals, the proof of identity must consist of at least the signature of the purchaser, a driver's license and one other form of identification. It is recommended that the second form of identification should corroborate the first and should be valid in its own right. If an individual presents an identification card issued by an appropriate state authority in lieu of a driver's license, such identification is acceptable provided that it contains the individual's name, address, a unique identification number, and the individual's photograph. A record, preferably a photocopy, should be kept of proof of identity information.

For new customers that are not individuals or cash customers, the regulated person must establish the identity of the authorized purchasing agent(s) and have on file that person's signature, electronic password or other identification. Once the authorized identity has been established the agent list may be updated annually rather than on each order.

For electronic orders, the identity of the purchaser shall consist of a computer password, identification number or some other means of identification consistent with electronic orders.

For an export transaction, proof of identity is to be accompanied by a good faith inquiry to verify the existence and validity of the foreign business entity. This can be done by verifying the business telephone listing through international telephone information, checking the firm's listing in international or foreign national chemical or commerce directories or trade publications, confirmation through foreign subsidiaries of the U.S. regulated person, or verification through the commercial attache of the embassy of the country of destination. Official documents provided by the purchaser may confirm the existence and apparent validity of the business entity.

Any exports to individuals or exports paid in cash are suspect and should be handled as such. For such exports, the regulated person must obtain from the purchaser or independently seek to confirm clear documentation which proves the person is properly identified such as through foreign identity documents, driver's license, passport information and photograph, etc. Any regulated person who fails to adequately prove the identity of the other party to the transaction may be subject to the specific penalties provided for violations of law related to regulated transactions in listed chemicals.

Record Keeping Requirements

Persons Required to Keep Records

Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine must keep a readily retrievable record of the transaction. Distribution records are required if the cumulative amount for multiple transactions to a person within a calendar month exceeds the threshold. Thresholds can be found in *Appendix B* and *Appendix C.*

21 U.S.C. § 830 and 21 CFR Part 1310

Contents of Regulated Transaction Records

21 CFR § 1310.06

Each record for a domestic transaction must contain the following information:

1. The name, address, and if required, the DEA registration number of each party to the regulated transaction.
2. The date of the transaction.
3. The name, quantity, and form of packaging of the listed chemical, or a description of the tableting machine or encapsulating machine (including make, model and serial number).
4. The method of transfer (company truck, picked up by the customer, etc.).
5. The type of identification used by the purchaser and any unique number of that identification.

Location and Availability of Records

21 CFR § 1310.04

A record of a regulated transaction is required to be kept at the business location where the transaction occurred. As an alternative, the record can be maintained at a single, central location which has been provided in writing and sent to the Special Agent in Charge of the local DEA Division Office by registered or certified mail (return receipt requested).

A regulated person with more than one place of business where a record is required to be kept must devise a record keeping system that detects purchases which are made at multiple locations to circumvent the cumulative threshold requirements.

Maintenance of Records

21 CFR § 1310.04

A record must be kept for two years from the date of transaction.

Reports to the Drug Enforcement Administration

21 U.S.C. § 830 and
21 CFR Part 1310

Types of Required Reports

In addition to periodic written reports required of bulk manufacturers and certain mail order distributors, there are four events that require prompt oral reporting to DEA.

Oral Reports

21 CFR § 1310.05

There are four types of transactions specified in the CSA which require a regulated person to make oral notification to the Special Agent in Charge, or a designee, of the local DEA Division Office whenever possible. The oral report must be made as soon as possible, and as far in advance of the conclusion of the regulated transaction, as possible. A written report of a transaction listed in paragraphs 1, 3, and 4 below is required to be sent to that office within 15 days after the regulated person becomes aware of the circumstances of the event. The four circumstances are:

1. Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law.

2. Any proposed regulated transaction with a person whose description or other identifying characteristic has been previously furnished by DEA to the regulated person. Such a transaction may not be completed unless the transaction is approved by DEA.

3. Any unusual or excessive loss or disappearance of a listed chemical that is under the control of the regulated person. The regulated person responsible for reporting a loss in transit is the supplier.

4. Any regulated transaction involving a tableting or encapsulating machine.

Recognizing Suspicious Orders

21 U.S.C. § 830 (b)(1)(A)

The law, 21 U.S.C. § 830 (b)(1)(A), requires that each regulated person shall report to the Attorney General any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. While reporting suspicious orders to DEA is required by law, the manner in which industry addresses the requirement determines its effectiveness.

In 1998 representatives of the chemical industry, including those whose products contain pseudoephedrine, phenylpropanolamine and other chemicals sought by drug traffickers, met in the Suspicious Orders Task Force with representatives of federal, state and local law enforcement and prosecutors. The Suspicious Orders Task Force considered issues relating to the diversion of these products. Industry representatives helped develop guidelines and expressed a willingness to distribute them through industry publications. They also agreed to incorporate the guidelines into existing employee training programs. One set of guidelines is the “Suspicious Orders Identification Criteria” for recognizing potential diversion at all levels of the distribution chain. Another set of guidelines is for use in automated tracking systems. See *Appendix E* for suspicious order identification criteria.

When a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicions. In addition to making the required reports, the transaction should not be completed until the customer is able to eliminate the suspicions. The distributor may have to forego some transactions. When DEA reviews distributor decisions, minor events are not cause for government action. At the same time a regulated person who fails to implement a system to prevent diversion will be closely scrutinized and if warranted, may be subject to civil, administrative, or criminal penalties.

The Task Force concluded that the term “suspicious order” had different meanings at different levels of the manufacturing and distribution chain. Accordingly, the recommendations of the Task Force and the definition of “suspicious” are specific for each group: Importers & Manufacturers; Wholesale Distributors; and Retail Distributors. Task Force findings appear in the appendices.

Bulk Manufacturers’ Reports

Regulated bulk manufacturers of listed chemicals are required to submit manufacturing, inventory, and use data on an annual basis to DEA, Drug and Chemical Evaluation Section, Washington, D.C. 20537. Reports are due by March 15 of the year immediately following the calendar year in which the inventory took place. Details of reporting requirements appear in 21 CFR §1310.05(d) and §1310.06(h).

Reports of Mail Order Distributions

21 U.S.C. § 830 (b)(3)

Each regulated person who engages in a transaction with a non-regulated person (a consumer or end-user who does not re-distribute) which involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals) via postal service, private carrier or commercial carrier, is required to submit a monthly report of all such transactions regardless of the size of the transaction.

The reports must include the name of the purchaser; the quantity and form of the ephedrine, pseudoephedrine, or phenylpropanolamine purchased; the date of each transaction; the address to which the product was sent; and such other items of information which DEA may by regulation require. Reports should be sent to the Chemical Control Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537.

The following distributions of drug products to non-regulated persons are exempted from the mail order reporting requirements:

1) Distributions of sample packages of drug products when those packages contain not more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

2) Distributions by retail distributors that may not include face-to-face transactions, to the extent that such distributions are consistent with the activities of a retail distributor.

3) Distributions to a resident of a long term care facility, or to a long term care facility for dispensing to or use by a resident of that facility.

4) Distributions in accordance with a valid prescription.

5) Exports which have been reported to DEA under the transhipment reporting requirements (21 CFR 1313.31), or the international transaction reporting requirements (21 CFR 1313.32), or for which advance notification reporting requirements are waived (21 CFR 1313.21).

DEA may revoke exemptions for regulated persons whose distributions are found to violate the regulations.

Imports, Exports, and International Transactions

Import/Export Declaration - DEA Form 486

21 U.S.C. § 971 and 21 CFR § 1313.12, 21, 32, 34

An Import/Export Declaration, DEA Form 486, must be completed by each regulated person for each regulated import, export, or international transaction. For the first shipment to a new customer, this form must be received by DEA at least 15 days prior to the import, export, or international transaction of the listed chemical. The exceptions to the 15-day rule are explained in the following paragraphs. Failure to complete the DEA Form 486 entirely and accurately may result in the shipment being suspended.

General Waiver of Advance Notification Requirement

21 U.S.C. § 971 (e)(2), (3) and 21 CFR § 1313.12 (c)(2), (e), (f) and § 1313.21 (c)(2), (e), (f)

DEA may determine in some circumstances that effective diversion control does not require advance notification for a regulated import of a listed chemical or a regulated export to a specific country. In those circumstances, DEA may issue a regulation waiving the notification requirement and no Form 486 is required. The regulated person, however, must submit quarterly reports.

Waiver of 15-day Advance Notification Requirement for Regular Customers or Regular Importers

21 CFR § 1313.15, 24

The 15-day advance notification requirement for regulated imports and exports of a listed chemical by regular customers or suppliers may be waived in the circumstances listed below.

It is important to note that although the 15-day advance notification may be waived, the DEA Form 486 must be received by DEA, Chemical Control Section, on or before the date of importation or exportation. Form 486 should be mailed to: Drug Enforcement Administration, Chemical Control Section, P.O. Box 28346, Washington, D.C. 20038, or transmitted by facsimile to (202) 307-4702.

Criteria for Waiver of Advance Notification Requirement

For importers, the 15-day advance notification requirement may be waived for any regulated person with an established record as an importer. To have an established record as an importer, the regulated person must have imported a listed chemical[1] at least once within the past six months, or twice within the past 12 months from a foreign supplier. The term also means that the regulated person has provided DEA with the following information:

1. the name, DEA registration number (where applicable), street

address, telephone number, telex number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and
2. the frequency and number of transactions occurring during the preceding 12-month period.

For exporters, the 15-day advance notification requirement may be waived for any regulated person who has an established business relationship with a foreign customer. An established business relationship with a foreign customer means that the regulated person has exported a listed chemical[2] at least once within the past six months, or twice within the past 12 months to a foreign manufacturer, distributor, or end user of the chemical that has an established business in the foreign country with a fixed street address. The term also means that the regulated person has provided DEA with the following information:

1. the name and street address of the chemical exporter and of each regular customer,
2. the telephone number, telex number, contact person, and where available, the facsimile number for the chemical exporter and for each regular customer,
3. the nature of the regular customer's business (i.e. importer, exporter, distributor, manufacturer, etc.) and if known, the use to which the listed chemical or chemicals will be applied,
4. the duration of the business relationship,
5. the frequency and number of transactions occurring during the preceding 12-month period,
6. the amounts and the listed chemical or chemicals involved in regulated transactions between the chemical exporter and the regular customer,
7. the method of delivery, and
8. other information that the chemical exporter considers relevant for determining whether a customer is a regular customer.

Disqualification of Waiver

21 U.S.C. § 971 (c) and 21 CFR § 1313.15 (c), § 1313.24 (e)

If there are grounds to believe that the chemical being imported or exported may be diverted to the clandestine manufacture of a controlled substance, DEA may disqualify the importer or exporter

[1]A regular importer of any of these chemicals – acetone, methyl ethyl ketone, or toluene – is qualified as a regular importer of all three chemicals, unless DEA notifies an importer to the contrary.

[2]A regular customer of any one of these three chemicals – acetone, methyl ethyl ketone, or toluene – is qualified as a regular customer of all three chemicals, unless DEA notifies an exporter to the contrary.

from the "regular customer" or regular importer status and thereby terminate the waiver of the advance notification requirement. A written notice explaining the reasons for such disqualification will be provided. The regulated person is entitled to a hearing within 45 days after written request.

Exports in Violation of Foreign Laws

21 CFR § 1313.25

It is incumbent upon the exporter, broker or trader to assure that each chemical export from the United States complies with the laws and regulations of the destination country. Exporters may contact DEA Office of Diversion Control, Chemical Control Section, for information on a specific country. If a shipment is found to be in violation of the laws of the foreign country, the exporter is subject to a penalty of up to 10 years imprisonment under 21 U.S.C. 960(d), and 18 U.S.C. 3571(3) provides for a $250,000 fine for an individual, and a $500,000 fine for an organization for each violation.

Execution of the Import/Export Declaration - DEA Form 486

21 CFR § 1313.12-14, 21-23, 32

The Import/Export Declaration, DEA Form 486, is a three-part form that may be acquired from the nearest DEA office. A DEA Form 486 must be completed by each regulated person for each regulated import, export, or international transaction. Form 486 is distributed as follows:

1. Copy 1 is to be retained by the importer, exporter, or broker/trader as an official record of the import, export, or international transaction;
2. Copy 2 serves as the notification copy. To assure that the completed copy 2 of the DEA Form 486 is received as soon as possible by DEA, it should be mailed to: Drug Enforcement Administration, P.O. Box 28346, Chemical Control Section, Washington, D.C. 20038.
3. Copy 3 is presented to the U.S. Customs Service:
   a. For **imports,** with the customs entry form.
   b. For **exports,** at the port of exit along with the Department of Commerce Shipper's Export Declaration for each export of a listed chemical.
   c. **For international transactions involving a broker or trader,** copy 3 is retained by the broker or trader as the official record of the international transaction. Declaration forms must be retained for two years.

If the 15-day advance notice has been waived for an import or export, it must be so indicated on the DEA Form 486 by checking the appropriate block (1c.) If a waiver has been granted, the DEA Form 486 must be received in Headquarters on or before the date of the import or export.

If a waiver has not been granted, the DEA Form 486 must be received by DEA at least 15 days prior to the date of import, export, or other international transaction.

The completed copy may be sent to DEA via electronic facsimile if desired. The DEA import/export facsimile number is (202) 307-4702.

Transshipment Through the United States

21 CFR § 1313.31

A chemical imported for transshipment or transit through the United States for immediate exportation is subject to notification requirements if the quantity equals or exceeds the threshold amount. DEA must be notified at least 15 days prior to the proposed transshipment date. The notification must be in the form of a notice or letter (not a DEA Form 486) providing pertinent details of the transshipment and must be received by DEA at least 15 days prior to the proposed transshipment date. The notification either may be mailed to the Drug Enforcement Administration, PO Box 28346, Washington, D.C. 20038, or may be sent via electronic facsimile to (202) 307-4702. The following details must be included:

1. The date the notice was executed;
2. The complete name and description of the listed chemical as it appears on the label or container;
3. The name of the chemical as it appears in 21 CFR §1310.02 and as listed in this manual;
4. The number of containers and the size or weight of each container for each listed chemical;
5. The net weight of each listed chemical given in kilograms;
6. The gross weight of the shipment given in kilograms;
7. The name, address, telephone number, business of foreign exporter, telex number, and, where available, the facsimile number;
8. The foreign port of exportation;
9. The approximate date of exportation;
10. The complete identification of the exporting carrier;
11. The name, address, business, telephone number, telex number, and, where available, the facsimile number of the importer, transferor, or transshipper;
12. The U.S. port of entry;
13. The approximate date of entry;
14. The name, address, telephone number, telex number, business of the consignee and, where available, the facsimile number of the consignee at the foreign port of entry;
15. The shipping route from the U.S. port of exportation to foreign port of entry at final destination;
16. The approximate date of receipt by the consignee at the foreign port of entry; and
17. The signature of the importer, transferor, transshipper, or agent, accompanied by the agent's title.

Returned Export

21 CFR § 1313.22 (e)

When an export of a listed chemical is refused, rejected or otherwise deemed undeliverable, it may be returned to the U.S. chemical exporter of record. A brief written notification (not a DEA Form 486) must be sent to DEA within a reasonable period of time outlining the circumstances. This explanation must be sent to the following address: Drug Enforcement Administration, Chemical Control Section, P.O. Box 28346, Washington, D.C. 20038. This does not apply to a shipment that has cleared foreign customs, been delivered and accepted by the foreign consignee. The application of this provision requires that rejection of the chemical by the consignee occur within reasonable proximity to the delivery (i.e., the "acceptance" of the chemical would be indicated by such events as full payment for the chemical and its introduction into inventory). A return to a third party in the United States will be regarded as an import.

Special Policy Regarding Exports of Certain Chemicals to Colombia

In March, 1996, the United States Government (U.S.G.) took steps to decertify Colombia's status as a nation actively cooperating with the United States on drug control. DEA has historically experienced great difficulty in determining the legitimacy and final destination of exports of chemicals from the United States to Colombian companies. Additionally, DEA is unable to rely on the Colombian government to insure that listed chemicals imported from the United States and other sources are not diverted to illicit drug manufacture. Following the U.S.G.'s decertification, DEA revoked regular customer status for all U.S. exports of the following cocaine essential chemicals to Colombia: acetone, potassium permanganate, MEK, MIBK, toluene, and ethyl ether. Despite the fact that since then Colombia has become conditionally certified, DEA continues to employ a heightened standard of review to scrutinize proposed exports and transshipments to Colombia because of the high probability that these chemicals may be diverted to the clandestine manufacture of cocaine. Details can be found in the Federal Register Notice dated March 28, 1996, pages 13759-13760 which establishes and explains this policy

(Appendix F).

Suspension of Shipments

21 U.S.C. § 971 (c) and 21 CFR § 1313.41

The Administrator may suspend any importation or exportation of a listed chemical based on evidence that the chemical may be diverted to the clandestine manufacture of a controlled substance. DEA will provide written notice to the regulated person explaining the legal and factual basis of the suspension. The regulated person may request an administrative hearing to determine the issues involving the suspension. A request for a hearing must be made within 30 days after receipt of the suspension notice.

Confidentiality

DEA collects confidential business information (CBI) from required reports and may collect CBI in the course of investigations. With respect to the chemical program, the release of CBI that is protected from disclosure under Exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. § 552 (b)(4) is governed by Section 830(c) of the CSA (21 U.S.C. § 830 (c)) and the Department of Justice procedures set forth in 28 CFR §16.7.

The CSA (21 U.S.C. § 830) provides that information that is protected from disclosure under Exemption 4 may only be released in circumstances related to the enforcement of controlled substance or chemical laws, customs laws, or for compliance with U.S. obligations under treaty or international agreements. The Department of Justice procedures establish that if a FOIA request is received for release of information that is protected under Exemption 4, the submitter of the protected information must be notified of such a request, given an opportunity to object to the disclosure, and allowed to provide justification as to why the information should not be disclosed.

In addition to the statutory and regulatory requirements, DEA has established internal guidelines governing the handling of CBI, including provisions that the material be maintained in locked containers, that access to the information be on a need-to-know basis, and that any disclosure under Section 830 be made only pursuant to a non-disclosure agreement by the receiving party.

regular customer of all three of these chemicals, unless DEA notifies an exporter to the contrary.

3

4 The MCA provides that retail sales of ordinary over-the-counter products in face-to-face transactions to individuals for personal

Appendix A

Identification Codes for Listed Chemicals[1]

The following section presents the DEA Code, the Harmonized Code, and the Chemical Abstract Number for List I and List II chemicals. Note that individual salts, isomers, esters, salts of esters, and salts of isomers have unique Chemical Abstract Numbers.

Chemical	DEA Code	Harmonized Code	New Harmonized Code	Chemical Abstract Number
List I				
N-Acetylanthranilic acid *and its salts and esters*	8522	2924.29.4700	2924.29.7590	[89-52-1]
Anthranilic acid *and its salts and esters*	8530	2922.49.3700	2922.43.0000	[118-92-3]
Benzaldehyde	8256	2912.21.0000	2912.21.0000	[100-52-7]
Benzyl cyanide	8735	2926.90.4700	2926.90.4700	[140-29-4]
Ephedrine *and its salts, optical isomers, and salts of optical isomers*	8113	2939.40.5000	2939.41.0000	[299-42-3]
Ergonovine *and its salts (Tariff name: Ergometrine)*	8675	2939.60.0000	2939.61.0000	[60-79-7]
Ergotamine *and its salts*	8676	2939.60.0000	2939.62.0000	[113-15-5]
Ethylamine *and its salts*	8678	2921.19.1000	2921.19.1000	[75-04-7]
Gamma-butyrolactone	2011	2932.29.6000	2932.29.5010	[96-48-0]
Hydriodic acid (57%)	6695	2811.19.6050	2811.19.6050	[10034-85-2]
Isosafrole	8704	2932.90.6000	2932.91.0000	[120-58-1]
Methylamine *and its salts*	8520	2921.11.0000	2921.11.0000	[74-89-5]
3, 4-Methylenedioxyphenyl-2-propanone *(Tariff name: 1-(1,3-benzodioxol-5-yl)-2-propanone)*	8502	2932.90.6000	2932.92.0000	[4676-39-5]
N-Methylephedrine *and its salts, optical isomers, and salts of optical isomers*	8115	2939.40.0050	2939.49.0000	[522-79-4]
N-Methylpseudoephedrine *and its salts, optical isomers, and salts of optical isomers*	8119	2939.40.0050	2939.49.0000	[14222-20-9]
Nitroethane	6724	2904.90.0000	2904.90.0000	[79-24-3]
Norpseudoephedrine *and its salts, optical isomers, and salts of optical isomers*	8317	2939.40.5000	2939.49.0000	[429-39-7]
Phenylacetic acid *and its salts and esters*	8791	2916.33.1000	2916.34.1000	[103-82-2]
Phenylpropanolamine *and its salts, optical isomers, and salts of optical isomers*	1225	2939.40.0050	2939.49.0000	[14838-15-4]
Piperidine *and its salts*	2704	2933.39.9000	2933.32.1000	[110-89-4]
Piperonal	8750	2932.90.3000	2932.93.0000	[120-57-0]
Propionic anhydride	8328	2915.90.5000	2915.50.5000	[123-62-6]
Pseudoephedrine *and its salts, optical isomers, and salts of optical isomers*	8112	2939.40.0010	2939.42.0000	[90-84-2]
Safrole	8323	2932.90.3700	2932.94.0000	[94-59-7]
List II				
Acetic anhydride	8519	2915.24.0000	2915.24.0000	[108-24-7]
Acetone	6532	2914.11.1000/ 2914.11.5000	2914.11.1000 /2914.11.5000	[67-64-1]
Benzyl chloride	8570	2903.69.2000	2903.69.2000	[100-44-7]
Ethyl ether	6584	2909.11.0000	2909.11.0000	[60-29-7]
Hydrogen chloride	6545	2806.10.0000	2806.10.0000	[7647-01-0]
Iodine	6699		2801.20.0000	[7553-56-2]
Methyl ethyl ketone (2-Butanone)	6714	2914.12.0000	2914.12.0000	[78-93-3]
Methyl isobutyl ketone	6715	2914.13.0000	2914.13.0000	[108-10-1]
Potassium permanganate	6579	2841.60.0010	2841.61.0000	[7722-64-7]
Sulfuric acid	6552	2807.00.0000	2807.00.0000	[7664-93-9]
Toluene	6594	2707.20.0000	2902.30.0000	[108-88-3]

[1]At present a total of 35 List I and List II chemicals, including drug products containing ephedrine, pseudoephedrine and/or phenylpropanolamine, are under Federal regulation. The Administration may add or delete a listed chemical by publishing a proposed change in the Federal Register at least 30 days prior to the proposed change, followed by a final rule. A person may petition to have a chemical added or deleted from the list by following the instructions in 21 CFR § 1310.02.

Appendix B

Thresholds for Regulated Transactions in List I Chemicals

List I Chemical	Threshold by base weight
N-Acetylanthranilic acid *and its salts and esters*	40 kilograms
Anthranilic acid *and its salts and esters*	30 kilograms
Benzaldehyde	4 kilograms
Benzyl cyanide	1 kilogram
Ephedrine *and its salts, optical isomers, and salts of optical isomers*	0 kilograms
Ergonovine *and its salts*	10 grams
Ergotamine *and its salts*	20 grams
Ethylamine *and its salts*	1 kilogram
Gamma-butyrolactone	0 kilograms[1]
Hydriodic acid (57%)	1.7 kilograms (or 1 liter by volume)
Isosafrole	4 kilograms
Methylamine *and its salts*	1 kilogram
3, 4-Methylenedioxyphenyl-2-propanone	4 kilograms
N-Methylephedrine *and its salts, optical isomers, and salts of optical isomers*	1 kilogram
N-Methylpseudoephedrine *and its salts, optical isomers, and salts of optical isomers*	1 kilogram
Nitroethane	2.5 kilograms
Norpseudoephedrine *and its salts, optical isomers, and salts of optical isomers*	2.5 kilograms
Phenylacetic acid *and its salts and esters*	1 kilogram
Phenylpropanolamine *and its salts, optical isomers, and salts of optical isomers*	2.5 kilograms
Piperidine *and its salts*	500 grams
Piperonal	4 kilograms
Propionic anhydride	1 gram
Pseudoephedrine *and its salts, optical isomers, and salts of optical isomers*	1 kilogram
Safrole	4 kilograms

[1]Until a permanent threshold is established in the Federal Register, all transactions are regulated.

Appendix B

Thresholds for List I Chemicals in Drug Products

List I Chemicals in Drug Products	Threshold by Base Weight			
	Distributions by retail distributors	Distributions by mail order	All other domestic distributions	Imports and exports
Ephedrine[1]				
– as the sole therapeutically significant ingredient	No threshold– all transactions regulated	No threshold– all transactions regulated	No threshold– all transactions regulated	No threshold– all transactions regulated
– in combination with therapeutically significant amounts of another medicinal ingredient	24 grams	24 grams	1 kilogram	1 kilogram
Pseudoephedrine[1]				
– other than ordinary over-the-counter products	24 grams	24 grams	1 kilogram	1 kilogram
– ordinary over-the-counter products	Exempt	24 grams	1 kilogram	1 kilogram
Phenylpropanolamine[1]				
– other than ordinary over-the-counter products	24 grams	24 grams	2.5 kilograms	2.5 kilograms
– ordinary over-the-counter products	Exempt	24 grams	2.5 kilograms	2.5 kilograms

[1]and its salts, optical isomers, and salts of optical isomers

Appendix B

Thresholds for Regulated Transactions in List II Chemicals

List II Chemicals	Domestic Sales		Imports and Exports	
	by volume	by weight	by volume	by weight
Acetic anhydride	250 gallons	1023 kgs	250 gallons	1023 kgs
Acetone	50 gallons[1]	150 kgs[1]	500 gallons	1500 kgs
Benzyl chloride	not applicable	1 kg	not applicable	4 kgs
Ethyl ether	50 gallons	135.8 kgs	500 gallons	1364 kgs
Hydrochloric acid[2]	not regulated	not regulated	50 gallons[2]	not applicable
Anhydrous hydrogen chloride[2]	not applicable	0.0 kgs	not applicable	27 kgs[2]
Iodine	not applicable	0.4 kgs	not regulated	not regulated
Potassium permanganate	not applicable	55 kgs	not applicable	500 kgs
Methyl ethyl ketone (2-Butanone)	50 gallons[1]	145 kgs[1]	500 gallons	1455 kgs
Methyl isobutyl ketone	not regulated	not regulated	500 gallons[2]	1523 kgs[2]
Sulfuric acid	not regulated	not regulated	50 gallons[2]	not applicable
Toluene	50 gallons[1]	159 kgs[1]	500 gallons	1591 kgs

[1]The cumulative threshold is not applicable to domestic sales of Acetone, Methyl ethyl ketone, and Toluene.

[2]Threshold applies to exports, transshipments, and international transactions to western hemisphere except Canada. Imports are not regulated.

Appendix C

Dosage Unit Conversion Tables for Drug Products*

Combination Ephedrine

Threshold as Base	#25mg Tablets HCl	#25mg Tablets Sulfate
Wholesale: 1000 grams	48,826	51,870
Retail: 24 grams	1,172	1,245

Pseudoephedrine

Threshold as Base	#120mg Tabs HCl	#120mg Tabs Sulfate	#60mg Tabs HCl	#60mg Tabs Sulfate	#30mg Tabs HCl	#30mg Tabs Sulfate
Wholesale: 1000 grams	10,172	10,806	20,344	21,613	40,688	43,225
Retail: 24 grams	244	259	488	519	976	1,037

Phenylpropanolamine

Threshold as Base	#75mg Tabs HCl	#25mg Tabs HCl	#12.5mg Tabs HCl	#6.25mg Tabs HCl
Wholesale: 2500 grams	41,371	124,112	248,224	496,449
Retail: 24 grams	397	1,191	2,383	4,766

*Retail transactions of ordinary over-the-counter products in face-to-face transactions to individuals for personal use and in quantities below these thresholds are not regulated transactions. **The 24-gram threshold on retail sales does not apply to ordinary over-the-counter non-liquid products sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base, and packaged in blister packs, each blister containing not more than two dosage units, or where the use of blister packs is technically infeasible, packaged in unit dose packets or pouches; and for liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or phenylpropanolamine base.** Distributors who engage in non-retail transactions must comply with the registration, record keeping, reporting, proof of identity and security requirements of the law.

Appendix D

Voluntary Cooperation

The legitimate industry has taken the opportunity to join the drive against drug abuse. Industry's voluntary initiatives demonstrate the importance that it places on keeping its products out of the hands of drug traffickers. Following are some ways in which the chemical industry has been able to assist in preventing diversion of chemicals into the illicit drug traffic.

Notifying in Advance of the 15-Day Export Requirement

The CSA requires that each regulated person who exports a listed chemical which meets or exceeds the threshold limits must notify DEA of the exportation not later than 15 days before the export is to take place. This 15-day period provides DEA the opportunity to verify the legitimacy of the consignee and to take necessary action to stop the shipment if it is determined that it may be diverted into the illicit traffic. Such verification must be coordinated with one or more foreign DEA offices and with the host country authorities, and it is, by nature, time-consuming. DEA's efforts can be greatly enhanced if industry notifies DEA of an export of a listed chemical as much in advance as possible.

Reporting of Changes in Amount Imported

The regulations require quarterly summary reporting by importers whose imports were made under waiver of advanced notification. (This is in addition to the filing of Form 486.) Voluntary reports in situations involving all List I chemical imports would be of great use in accurately capturing this critical import data, which does not now capture reductions to initially declared data.

Educating Subsidiary Companies

Frequently, a U.S. chemical supplier exports a listed chemical to a subsidiary company for further distribution. It is important that a U.S. chemical firm educate its subsidiaries with regard to the severity of the chemical diversion problem and encourage them to implement voluntary controls to prevent diversion and subsequent clandestine use of the chemical.

Examples of Voluntary Initiatives that Companies Have Taken

Several companies have implemented voluntary programs which go beyond the minimum required by law, to ensure that their products or operations do not become a part of the methamphetamine problem.

Following are examples of the voluntary programs undertaken by retail distributors and manufacturers/wholesale distributors.

Retail Distributors

1) Sale Quantity Limits: Several retailers established voluntary sales limits which are substantially lower than 24 grams, and include "blister pack" sales, although these are exempt from mandatory retail controls. Many retailers discontinued sales of 100 count or larger bottles of these products. These firms have concluded that the vast majority of their legitimate consumer sales are unaffected by these voluntary limits, and at the same time the limits ensure that their stores do not unwittingly become a source of supply for the illicit manufacture of methamphetamine.

2) Point of Sale Messages at Cash Registers: Separately or in conjunction with "sale quantity limits" programs implemented above, several companies whose stores have an electronic, or "point-of-sale" check out system, have programmed an operator message to appear on the cashier's register. This message indicates when a customer attempts to purchase more than the store's established limits for these over-the-counter (OTC) medications. In most cases, no other merchandise may be scanned until the cashier overrides the message.

3) Sign Postings: Several retailers posted signs on the shelves containing cold, flu, allergy, and asthma medications, as well as at the check out registers to notify their customers about their policy restricting the sale of products containing ephedrine, pseudoephedrine, or phenylpropanolamine. These signs have ranged from the company announcing that they are working in cooperation with DEA to a simple notification of the sale quantity limit.

4) Limiting Shelf Stock: Several companies are limiting the shelf space given to OTC products which contain pseudoephedrine or phenylpropanolamine, thus requiring any customer seeking an excessive amount of these products to make inquiries with store personnel. Some chain warehouses are also limiting the amount of stock any retail store may order, thus limiting the possibility of diversion. These actions will help prevent the loss of significant amounts of a store's stock of these products through theft.

5) Education of Employees: Several companies do not have electronic, or point-of-sale, check-out systems at their cash registers. However, they have established a program to inform employees of the company's policy concerning the restriction of OTC products containing ephedrine, pseudoephedrine or phenylpropanolamine and the names of products whose sales are limited.

6) Placing Selected Products behind the Counter: The monitoring of sales trends over time can identify unusual increases, indicating that perhaps products are being diverted to clandestine methamphetamine laboratories.

7) Notifying Law Enforcement: The participation of legitimate industry is an essential element in the fight against methamphetamine abuse, through such voluntary programs as those previously cited. Law enforcement relies on information provided by concerned citizens in order to effectively fight chemical diversion. The limiting of the number of OTC products that may be purchased at one time is an essential step. However, laboratory operators will seek out other

sources, especially those who may not be implementing such programs. Notifying local law enforcement of attempted excess purchases has proven useful.

Manufacturer/Wholesale Distributor Initiatives

1) Limitation of Product Line: Manufacturers and wholesale distributors have aggressively enhanced their role in preventing the diversion of these OTC products for the illicit manufacture of methamphetamine:

• In October 1997, the Methamphetamine Control Act placed controls on retailers engaging in "non-blister pack" single transaction sales of over 24 grams for products containing pseudoephedrine or phenylpropanolamine.

• Several manufacturers and custom label wholesale distributors discontinued their packages containing 100 or more count bottles of these OTC products, which are the sizes most preferred by traffickers. Small quantity "blister packs" increase the difficulty for clandestine laboratory operators using these tablets.

2) Education of Employees: Several manufacturers and wholesale distributors are also aware that the best offense is a good defense. These firms have developed educational programs for their employees and for their customers concerning the MCA. The programs include a drug abuse prevention message relating to methamphetamine and an explanation of the firm's corresponding voluntary program to ensure their products do not contribute to the illicit manufacture of methamphetamine. Such programs include suggested notification for employees of retail distributors as to what products are restricted under the MCA, and what to do if a retail customer attempts to purchase more than the designated amount of a restricted OTC medication.

3) List of OTC Products: Several major wholesalers have reviewed the sales and trend data for OTC products they distribute and which may be diverted for the illicit manufacture of methamphetamine. As a result, they have produced a distribution list and forwarded a courtesy copy to DEA. Such information, in conjunction with law enforcement intelligence, will be very useful in identifying sources of those products used in the illicit manufacture of methamphetamine.

If the remainder of the chemical industry will undertake these and similar voluntary measures, a tremendous impact can be made on the availability of illicitly-produced controlled substances in the United States.

Appendix E-1

Suspicious Orders Task Force

PubLaw 104-237 Title V, § 504, Oct 3, 1996
The entire report can be viewed on the Diversion Control internet site:
www:deadiversion.usdoj.gov
Choose "Publications," then "program reports"

The law, 21 U.S.C. § 830(b)(1)(A), requires that each regulated person shall report to the Attorney General any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. While the CSA requires reporting of suspicious orders, the manner in which industry addresses the requirement determines its effectiveness.

Representatives of government and the chemical industry worked together in 1998 in the Suspicious Orders Task Force to develop voluntary guidelines for recognizing suspicious orders. The Task Force guidelines, entitled "Suspicious Orders Identification Criteria," were endorsed by the Attorney General and widely accepted by industry. The criteria, which are for voluntary use, are specific for each segment of the chemical distribution industry: Importers & Manufacturers; Wholesale Distributors; and Retail Distributors. Task Force guidelines appear in the appendices.

The Task Force recommended that manufacturers of retail over-the-counter drug products containing List I chemicals utilize "ordinary over-the-counter" packaging as defined in the MCA and that products packaged differently be prepared and distributed only for prescription use as defined by the Food, Drug and Cosmetic Act. The industry has widely accepted this recommendation. Industry has distributed the guidelines and incorporated them into employee training programs.

Suspicious Orders Identification Criteria

Each regulated entity is most familiar with its customers and circumstances surrounding the orders it processes. The chemical industry must use its best judgment in identifying suspicious orders. The following criteria are provided in order to assist the industry in identifying suspicious orders.

All Levels / All Chemicals (* indicates that criterion may not apply to all retail settings)

New customer or unfamiliar representative or established customer who begins ordering listed chemicals.*

Customers who don't seem to know industry practice or who fail to provide reasons for an order at variance with accepted legitimate

industry practice.

Customer whose communications are not prepared or conducted in a professional business manner.*

Customer who provides evasive responses to any questions or is unable to supply information as to whether chemicals are for domestic use or for export.

Customer who has difficulty pronouncing chemical names.

New customers who don't seem to know Federal or state government regulations.*

Customer whose stated use of listed chemicals is incompatible with destination country's commercial activities or consignee's line of business.*

Customers who want predominantly or only regulated chemicals.

Customers who want multiple regulated or surveillance list (see Appendix G for Special Surveillance List) products, particularly if in contrast to customary use and practice.

Customer who is vague or resists providing information about firm's address, telephone number, and reason for seeking that chemical.*

Customer who provides false or suspicious addresses, telephone numbers or references.

Customer who is vague or will not furnish references for credit purposes.*

Customer who refuses or is reluctant to establish a credit account or provide purchase order information.*

Customer who prefers to pay by cashiers check, postal money order, etc.

Customer who desires to pay cash.*

Customer who wants to pick up the chemicals outside of normal practice in the supplier's experience.

Customer with little or no business background available.*

An established customer who deviates from previous orders or ordering methods.

Customers who want airfreight or express delivery.

Customers who want chemicals shipped to a PO Box or an address other than usual business address. (e.g., residence address)

Customer using a freight forwarder as ultimate consignee.

Customer who requests unusual methods of delivery or routes of shipment.

Customer who provides unusual shipping, labeling, or packaging instructions.

Customer who requests the use of intermediate consignees whose location or business is incompatible with the purported end user's nature of business or location.

Above threshold hydrochloride gas or iodine sales to a non-commercial customer.

Distributor (Non-retail) of Regulated OTC Products

Customers who don't want to tell you what area they will resell into.

Customers who don't want to tell you in what volumes they will resell.

Customers who refuse to tell you who their customers are.

Customers who don't have limits on resales.

Customers who push to buy more than your sales limit.

Customers who repeatedly buy your sales limit at the shortest interval you set.

Customers who don't know customers' limits on individual resales.

Customers who resell to non-traditional outlets for regulated OTC products, e.g., hair salons, head shops, drug paraphernalia stores, liquor stores, record stores, video shops, auto parts stores.

Customers who resell large volumes into the "independent convenience store" market.

Any customer who asks for large bottle sizes, 60 count or higher.

Customers who buy only the largest size available.

Customers that don't sell other pharmaceutical products or appear to sell those other products in token amounts.

Any customer that resells multiple cases that flow through to individual retail outlets.

New customers who want to sell regulated OTC products into California, Arizona, Nevada, Oregon, Utah, Washington, New Mexico, Texas, Kansas, Missouri, Arkansas.

Any customer who wants to sell to an outlet relocated from California, Missouri, or Kansas to any of the states identified in the prior sentence.

Any customer who wants to export, particularly to Mexico, Canada, or Southeast Asia.

Customers who will not provide you with evidence of registration with DEA. (Or having applied by the following deadlines: Nov 13, 1995 for single entity ephedrine; July 12, 1997 for ephedrine combination products; Dec 3, 1997 for pseudoephedrine and phenylpropanolamine products.)

Customers who will not provide you with evidence of applicable state registrations/licenses.

Customers who sell mail order and who don't report sales to DEA monthly. (Note they must also be registered.)

Nominal retail customers who sell above the Federal, "Retail," 24 Gm individual sale limits.

Wholesale Drug Distribution Indicators

Individual pharmacies that intend to export.

Individual pharmacies or chains that won't set a voluntary limit for individual sales at some fraction of the Federal limit to qualify as a retail outlet.

Pharmacies that stock large shelf volumes in stores that have repeated thefts or other sales problems.

Appendix E-2

Factors Which May Suggest a Suspicious Transaction

Retail Level - Regulated Products and/or Combination Purchases

OTC customers who ask for more than the transaction limit in effect.

Customers who are part of a group, each of whom buys the transaction limit.

Customers who buy the transaction limit on the same day and/or repeatedly within a few days.

Customers who buy only the largest size available at the transaction limit.

Customers who buy other methamphetamine processing products at the same time as the regulated products (alcohol, Coleman fuel, acetone, road flares, drain cleaners, iodine, muriatic acid, rock salt, starting fluid (ether), dry gas (alcohol), coffee filters, large amounts of matches, etc.)

Customers who indicate they will resell or export.

Iodine customers who don't have a legitimate reason for the purchase or who don't have an articulate reason for the volume requested.

Customers who purchase iodine crystals or pellets with any otheritem from the surveillance list.

Customers who want to pay cash when other forms of payment would be customary.

There may be a legitimate explanation for a purchase that represents one or more of these factors. The list is presented as a guide to instruct retailers and their employees as to which transactions may be suspicious.

Appendix E-3

Suspicious Order Reporting System for Use in Automated Tracking Systems

Terms & Definitions

This voluntary formula is for use by distributors to wholesale and retail levels. The formula calculates the quantity which, if exceeded in one month, constitutes an order which **may** be considered excessive or suspicious and therefore require reporting to DEA.

1) Add purchase quantities for the last 12 months for all customers within same Distribution Center and for customer type (Hospital, Pharmacy or Other) for any List I chemical containing item stocked by the Distribution Center.

2) Add Customer months for every record used in above total. (Months within the last 12 that customer purchases of the item were not zero.)

3) Divide total quantity purchases by the total customer months.

4) Then multiply by the factor below to give the maximum amount that the customer can order per month before showing up on the suspicious order report.

Note: Factor equals 3 for C-II and C-III Controlled Substances Containing List I Chemicals and 8 for C-III-IV-V Controlled Substances and non-Controlled OTC products containing List I chemical items.

5) At the end of each month, a report will be transmitted to DEA (separate reports for List I Chemicals and Schedule II-V Controlled Substances) of all purchases of List I Chemicals and/or C-II-V Controlled Substances and List I containing OTC items by any customer whose purchase quantities exceed the parameters (above) any (2) consecutive months or in three (3) of any moving six (6) month period.

Using a computer to manage and report on high volume transaction business activities with extremely short order cycle times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious.

Appendix F

Dated: March 18, 1996.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 96-7385 Filed 3-27-96; 8:45 am]

BILLING CODE 4410-09-P

21 CFR 1313

[DEA Number 145N]

Export of Chemicals From the United States to Colombia; Policy Statement

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Policy statement.

SUMMARY: Notice is hereby given that regular customer status for Colombian customers is being revoked under Section 1018(c)(1) of the Controlled Substance Import Export Act (CSIE) (21 U.S.C. 971(c)(1)). Each U.S. exporter is being informed by letter that they must notify DEA at least 15 days in advance of shipment of certain chemicals listed in 21 CFR 1310.04, if the shipment is from the United States with an ultimate destination of Colombia. Moreover, in view of the danger that chemical shipments may be diverted into the illicit manufacture of cocaine, a heightened review process will be instituted for such exports and for transhipments. The exception under Title 21, Code of Federal Regulations (21 CFR), Section 1313.24, allowing exporters to notify DEA as late as the day of shipment for transactions between a "regulated person" and a "regular customer" will not apply to shipments of certain chemicals to Colombia until further notice.

EFFECTIVE DATE: March 28, 1996.

FOR FURTHER INFORMATION CONTACT: William Wolf, Chief, Chemical Operations Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307-7204.

SUPPLEMENTARY INFORMATION: The following is a statement of policy by the Drug Enforcement Administration (DEA) under the Controlled Substances Act, as amended by the Chemical Diversion and Trafficking Act of 1988 (CDTA), regarding exports of certain listed chemicals from the United States to Colombia.

On March 1, 1996, the President of the United States, under the Annual Certification Procedures Act (22 U.S.C. Section 2291j), moved to decertify Colombia's status as a nation actively cooperating with the United States to stem the clandestine manufacture and trafficking of illegal drugs. This action was taken in response to overwhelming evidence of rampant drug-related corruption at the highest levels of the Colombian government. In direct contravention of efforts by Colombian law enforcement officials and the judicial sector to root out drug-related corruption, elements of the Colombian government have systematically undermined and publicly attacked these efforts while failing to support the efforts of Colombian law enforcement to strengthen the nation's institutions to combat the destructive effects of narcotics traffickers.

These problems have also adversely affected the ability of the Colombian Government to insure that listed chemicals imported from the U.S. and other sources are not diverted into the illicit manufacture of cocaine.

At a time when the Colombian government's commitment to combating narcotic trafficking has deteriorated, as evidenced by shifting the import permit approvals outside the existing infrastructure for chemical control, DEA data reveals a 57% increase between 1990 and 1995 in the sales to Colombia of List II solvents that are used in the clandestine manufacture of cocaine. These sales by U.S. chemical firms, which were based primarily upon Colombian authorization, are estimated by the Colombian Director of Customs to comprise 58% of the listed chemicals now imported into Colombia and, unfortunately, coincide with continued large scale illicit cocaine production within Colombia. DEA has concluded, therefore, that all shipments to Colombia of certain chemicals may be diverted to the clandestine manufacture of a controlled substance.

The CDTA, the Domestic Chemical Diversion Control Act (DCDCA) and the implementing regulations have established a system of recordkeeping and reporting requirements that provide DEA with a mechanism to track domestic and international movement of listed chemicals in order to prevent their being diverted for use in the clandestine manufacture of controlled substances.

Section 1018(a) of the CSIE (21 U.S.C. 971(a)), as amended by the CDTA, provides that "each regulated person who imports or exports a listed chemical shall notify the Attorney General of the importation or exportation not later than 15 days before the transaction is to take place." In accordance with Section 1018(b) (21 U.S.C. 971(b)), this requirement is modified by 21 CFR 1313.24 where the transaction is between a "regulated person" and a "regular customer." Under normal circumstances, exporters are allowed to ship listed chemicals to regular customers with notification as late as the day of shipment.

A person located in the United States who is a broker or trader for an international transaction of a listed chemical is subject to all of the notification, reporting, recordkeeping, and other requirements placed upon exporters of listed chemicals. No waiver of the 15-day advance notice is permitted under Section 1313.31 for importations and exportations for transhipment purposes of threshold quantities of listed chemicals.

Regardless of whether the shipment is a direct export or a transhipment, DEA has the obligation to examine the notification in order to determine if the shipment is legitimate and that the chemical will not be diverted to the illicit manufacture of controlled substances. Due to the distribution network within Colombian, where large quantities of the chemicals used in the clandestine manufacture of illegal controlled substances are redistributed by the importing customer, becoming "regular customer" status on the importer is ineffective in assuring legitimate usage.

As underscored by the President's action to decertify Colombia as a cooperating nation due to widespread corruption, DEA is unable to determine the legitimacy of shipments of the specified chemicals or to rely on import permits and other documentation issued by the Colombian Government that the above chemicals are not being diverted for use in the clandestine manufacture of controlled substances. Although the Colombian National Police have been diligent and constructive in their efforts to monitor the legitimacy of chemicals imported into Colombia, its efforts have been handicapped by inadequate political and resource support. DEA has no confidence that those customers previously submitted as regular customers, nor those who would become regular customers in the future, as specified in 21 CFR 1313.24, are not diverting the above chemicals to the illicit drug traffic. Therefore, in the absence of a way to determine with any reasonable degree of certainty that chemical shipments will not be diverted, pursuant to Section 1018(c)(1) of the CSIE (21 U.S.C. 971(c)(1)), DEA will act to disqualify regular customer status for Colombian importers of MEK, MIBK, acetone, toluene, potassium permanganate, and ethyl ether. Accordingly, each U.S. exporter is being informed by letter that for all shipments of these chemicals to Colombia, the exporter must now file a Chemical

Export Declaration (DEA Form 486) at least 15 days in advance of the shipment date in accordance with 21 CFR 1313.21 for every shipment of a threshold amount of the above listed chemicals to Colombia. All subsequent shipments of any of the identified chemicals to the same customer will continue to require 15 day advance notice and evidence of a documented legitimate need.

Furthermore, because DEA has concluded that all shipments to Colombia of the above chemicals may be diverted to the clandestine manufacture of a controlled substance, pursuant to 21 CFR 1313.41, it is DEA's intent to suspend such exports and imports for transhipment, in the absence of documented proof of ultimate legitimate use. Shipments of these chemicals will be closely monitored by DEA to determine whether the exporters have presented sufficiently detailed documentation for DEA to conclude that the ultimate users have the specific, legitimate need for the type and quantity of the chemical being purchased and, that the chemical will not be used for the clandestine production of controlled substances. Export declarations and Notices of Importation for Transhipment for the specified chemicals will be reviewed utilizing the following criteria:

A. Whether the U.S. exporter, broker, or foreign exporter for transhipment has shown that the end use for all of the chemical will be for a legitimate purpose;

B. If the importer is not the end user, whether all users or distributors through to the end users are identified to DEA with sufficient documentation to confirm the legitimacy of their chemical needs; and

C. Whether the quantity and type of chemical is consistent with the nature and size of each end user's business.

A person who knowingly or intentionally exports a listed chemical in violation of section 1018 shall be fined in accordance with Title 18, imprisoned not more than 10 years, or both (21 U.S.C. 960(d) (5) and (6)).

U.S. and foreign exporters, and brokers are cautioned to view every order of these or substitute chemicals from Colombia and other countries in the region with extreme caution. In view of the existing evidence that all shipments to Colombia of the above chemicals may be diverted to the clandestine manufacture of a controlled substance, firms should recognize that export declarations and Notices of Importation for Transhipment will be subjected to the heightened standard of review set forth herein with respect to the identity of the end users and the documented legitimacy of usage. Failure to meet this standard will result in the suspension of the shipment pursuant to 21 CFR 1313.41.

Dated: March 22, 1996.

Stephen H. Greene,

Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 96-7548 Filed 3-27-96; 8:45 am]

BILLING CODE 4410-09-M

Appendix G

Special Surveillance List of Chemicals, Products, Materials and Equipment Used in the Clandestine Production of Controlled Substances or Listed Chemicals

Background

The Comprehensive Methamphetamine Control Act of 1996 (MCA) makes it unlawful for any person to distribute a laboratory supply to a person who uses, or attempts to use, that laboratory supply to manufacture a controlled substance or a listed chemical, with reckless disregard for the illegal uses to which such laboratory supply will be put. Individuals who violate this provision are subject to a civil penalty of not more than $25,000; businesses which violate this provision are subject to a civil penalty of not more than $250,000. The term "laboratory supply" is defined as "a listed chemical or any chemical, substance, or item on a special surveillance list published by the Attorney General, which contains chemicals, products, materials, or equipment used in the manufacture of controlled substances and listed chemicals."

Special Surveillance List

Chemicals

All listed chemicals as specified in 21 CFR § 1310.02 (a) or (b) or 21 U.S.C. § 802 (34) or (35). This includes all chemical mixtures and all over-the-counter (OTC) products and dietary supplements which contain a listed chemical, regardless of their dosage form or packaging and regardless of whether the chemical mixture, drug product or dietary supplement is exempt from regulatory controls.

Ammonia Gas
Ammonium Formate
Bromobenzene
1,1-Carbonyldiimidazole
Cyclohexanone
1,1-Dichloro-1-fluoroethane (e.g., Freon 141B)
Diethylamine and its salts
2,5-Dimethoxyphenethylamine and its salts
Formamide
Formic Acid
Hypophosphorous Acid
Lithium Metal
Lithium Aluminum Hydride
Magnesium Metal (Turnings)
Mercuric Chloride
N-Methylformamide
Organomagnesium Halides (Grignard Reagents) (e.g., ethylmagnesium bromide and phenylmagnesium bromide)
Phenylethanolamine and its salts
Phosphorus Pentachloride
Potassium Dichromate
Pyridine and its salts
Red Phosphorus
Sodium Dichromate
Sodium Metal
Thionyl Chloride
ortho-Toluidine
Trichloromonofluoromethane (e.g., Freon-11, Carrene-2)
Trichlorotrifluoroethane (e.g., Freon 113)

Equipment

Hydrogenators
Tableting Machines
Encapsulating Machines
22 Liter Heating Mantels

Additional Information

The Special Surveillance List appeared as a Final Notice in the Federal Register on May 13, 1999. A Correction to the Final Notice appeared in the Federal Register on September 17, 1999.

Appendix H

DEA Diversion Field Offices

ALABAMA	**Birmingham DEA**
Northern	234 Goodwin Crest Birmingham, AL 35209 205-290-7150
Southern	**Mobile DEA** 900 Western America Circle Mobile, AL 36609 334-441-5831
ALASKA	**Seattle DEA** 400 2nd Avenue West Seattle, WA 98119 206-553-5990
ARIZONA	**Phoenix DEA**
Northern *Central*	3010 N. 2nd St. Phoenix, AZ 85012 602-664-5600
Southern	**Tucson DEA** 3285 E. Hemisphere Loop Tucson, AZ 85706 520-573-5500
ARKANSAS	**Little Rock DEA** 10825 Financial Pkwy. Little Rock, AR 72211-3557 501-324-5981
CALIFORNIA	**Fresno DEA**
Central	2444 Main St. Fresno, CA 93721 559-487-5402
South Central	**Los Angeles DEA** 255 E. Temple St. Los Angeles, CA 90012 213-894-2650
Northern	**Oakland DEA** P.O. Box 70301 Oakland, CA 94612 510-637-5600
CALIFORNIA	**Riverside DEA**
South Central	4470 Olivewood Ave. Riverside, CA 92501 909-328-6000
	Sacramento DEA 1860 Howe Ave. Sacramento, CA 95825 916-566-7401
Southern	**San Diego** 4560 Viewridge Ave. San Diego, CA 92123-1637 858-616-4325
Central Coastal	**San Francisco DEA** P.O. Box 36035 San Francisco, CA 94102 415-436-7854
Central	**San Jose DEA** One N. First St. San Jose, CA 95113 408-291-7235
CARIBBEAN	**San Juan DEA** P.O. Box 2167 San Juan, PR 00922-2167 787-775-1877
COLORADO	**Denver DEA** 115 Inverness Dr., E. Englewood, CO 80112 303-705-7300
Southern	Colorado Springs DEA 111 S. Tejon Colorado Springs, CO 80903 719-471-1749
CONNECTICUT	**Hartford DEA** 450 Main St. Hartford, CT 06103 860-240-3700

DELAWARE
Philadelphia DEA
600 Arch St.
Philadelphia, PA 19106
215-597-9540

DISTRICT OF COLUMBIA
Washington DEA
800 K St., NW
Washington, D.C. 20001
Metro Area 202-305-8800

FLORIDA
Miami DEA
8400 NW 53rd St.
Southeastern Miami, FL 33166
305-590-4980

Central
Orlando DEA
300 Internationl Pkwy.
Heathrow, FL 32746
407-333-7046

Northern
Tallahassee DEA
3384 Capital Circle NE
Tallahassee, FL 32308
850-942-8417

West Central
Tampa DEA
4950 W. Kennedy Blvd.
Tampa, FL 33609
813-288-1268

GEORGIA
Atlanta DEA
75 Spring St., SW
Atlanta, GA 30303
404-763-5861

Eastern
Savannah DEA
65 Park of Commerce #A
Savannah, GA 31405
912-447-1035

HAWAII
Honolulu DEA
Guam
Saipan
P.O. Box 50163
Honolulu, HI 96850
808-541-1930

IDAHO
Seattle DEA
Northern
400 2nd Avenue West
Seattle, WA 98119
206-553-5990

Southern
Boise DEA
607 N. 8th St.
Boise, ID 83702-5518
208-334-1620

ILLINOIS
Chicago DEA
Northern
230 S. Dearborn St.
Chicago, IL 60604
312-353-7875

Central
Springfield DEA
2875 Via Verde St.
Springfield, IL 62703
217-492-4504

INDIANA
Indianapolis DEA
575 N. Pennsylvania
Indianapolis, IN 46204
317-226-7977

Northern
Merrillville DEA
1571 E. 85th Ave.
Merrillville, IN 46410
219-681-7000

IOWA
Des Moines DEA
210 Walnut St.
Des Moines, IA 50309
515-284-4709

KANSAS
Kansas City DEA
8600 Farley
Overland Park, KS 66212
913-652-9127

KENTUCKY
Louisville DEA
600 Martin Luther King Jr. Pl.
Northern
Louisville, KY 40202
502-582-5908

Southeastern
London DEA
P.O. Box 5065
London, KY 40745-5070
606-862-4500

LOUISIANA
New Orleans DEA
3838 N. Causeway Blvd.
Metairie, LA 70002
504-840-1100

MAINE
Boston DEA
15 New Sudbury St.
Boston, MA 02203-0402
617-557-2100

MARYLAND
Baltimore DEA
200 St. Paul Pl.
Baltimore, MD 21202-2004
410-962-7580

MASSACHUSETTS
Boston DEA
15 New Sudbury St.
Boston, MA 02203-0402
617-557-2100

MICHIGAN
Detroit DEA
431 Howard St.
Detroit, MI 48226
313-234-4000

MINNESOTA
Minneapolis/St. Paul DEA
330 Second Ave., S.
Minneapolis, MN 55401
612-348-1729

MISSISSIPPI
Jackson DEA
100 W. Capitol St.
Jackson, MS 39269
601-965-4400

MISSOURI
St. Louis DEA
7911 Forsyth Blvd.
Eastern
St. Louis, MO 63105
314-538-4600

Western
Kansas City DEA
8600 Farley
Overland Park, KS 66212
913-652-9127

MONTANA
Denver DEA
115 Inverness Dr., E.
Englewood, CO 80112
303-705-7300

NEBRASKA
Des Moines DEA
210 Walnut St.
Des Moines, IA 50309
515-284-4709

NEVADA
Las Vegas DEA
600 Las Vegas Blvd. S.
Las Vegas, NV 89101
702-388-6635

NEW HAMPSHIRE
Boston DEA
15 New Sudbury St.
Boston, MA 02203-0402
617-557-2100

NEW JERSEY
Newark DEA
80 Mulberry St.
Northern
Newark, NJ 07102
Central
973-273-5060/5080

Southern
Camden DEA
1000 Crawford Pl.
Mt. Laurel, NJ 08054
609-968-4899

NEW MEXICO
Albuquerque DEA
301 Martin L King Ave., NE
Albuquerque, NM 87102
505-346-7419

NEW YORK
Buffalo DEA
28 Church St.
Central
Buffalo, NY 14202
Western
716-551-3391

Long Island DEA
175 Pinelawn Rd.
Melville, NY 11747
516-420-4540

New York DEA
99 Tenth Ave.
New York, NY 10011
212-337-1575

NORTH CAROLINA
Greensboro DEA
1801 Stanley Rd.
Greensboro, NC 27407
336-547-4219

NORTH DAKOTA
Minneapolis/St. Paul DEA
330 Second Ave., S.
Minneapolis, MN 55401
612-348-1700

OHIO
Cincinnati DEA
36 E. 7th St.
Southern
Cincinnati, OH 45202
513-684-3671

OHIO
Northern
Cleveland DEA
310 Lakeside Ave.
Cleveland, OH 44113
216-552-3705

Central
Columbus DEA
500 S. Front St.
Columbus, OH 43215
614-469-2595

OKLAHOMA
Oklahoma City DEA
9900 Broadway Extension
Oklahoma City, OK 73114-6323
405-475-7556

Northeastern
Tulsa DEA
7615 E. 63rd Pl.
Tulsa, OK 74133
918-459-9600

OREGON
Portland DEA
1220 SW 3rd Ave.
Portland, OR 97204
503-326-2447

PENNSYLVANIA
Philadelphia DEA
600 Arch St.
Eastern
Philadelphia, PA 19106
215-597- 9540

Western
Pittsburgh DEA
1000 Liberty Ave.
Pittsburgh, PA 15222
412-395-4502

PUERTO RICO
Caribbean DEA
P.O. Box 2167
San Juan, PR 00922-2167
787-775-1877

RHODE ISLAND
Boston DEA
15 New Sudbury St.
Boston, MA 02203-0402
617-557-2100

SOUTH CAROLINA
Columbia DEA
1835 Assembly St.
Columbia, SC 29201
803-253-3441

SOUTH DAKOTA
Des Moines DEA
210 Walnut St.
Des Moines, IA 50309
515-284-4709

TENNESSEE
Nashville DEA
801 Broadway
Nashville, TN 37203
615-736-2559

TEXAS
Dallas DEA
1880 Regal Row
Northern
Dallas, TX 75235
214-640-0850

Western
El Paso DEA
660 S. Mesa Hills Dr.
El Paso, TX 79912
915-832-6000

Northern
Ft. Worth DEA
819 Taylor St.
Ft. Worth, TX 76102
817-978-3455

Southern
Eastern
Houston DEA
1433 W. Loop S.
Houston, TX 77027-9506
713-693-3634

Central
Western
San Antonio DEA
10127 Morocco
San Antonio, TX 78216
210-525-2900

East
Tyler DEA
909 East SE Loop
Tyler, TX 75701-9665
903-534-0472

Central
Waco DEA
6801 Sanger
Waco, TX 76710
254-741-1920

UTAH
Salt Lake City DEA
348 East S. Temple
Salt Lake City, UT 84111
801-524-4156

VERMONT
Hartford DEA
450 Main St.
Hartford, CT 06103
860-240-3700

VIRGINIA
Richmond DEA
Central
8600 Staples Mill Road
Southern
Richmond, VA 23228
804-771-8163

WASHINGTON
Seattle DEA
400 2nd Avenue West
Seattle, WA 98119
206-553-5990

WEST VIRGINIA
Charleston DEA
2 Monongalia St.
Charleston, WV 25302
304-347-5209

WISCONSIN
Milwaukee DEA
1000 N. Water St.
Milwaukee, WI 53202
414-297-3395

WYOMING
Denver DEA
115 Inverness Dr., E.
Englewood, CO 80112
303-705-7300

Appendix I

Diversion Control Information on the Internet

The DEA Office of Diversion Control website is:
www.deadiversion.usdoj.gov

Other useful websites :

• for Federal Register or Code of Federal Regulations, U.S. Government Printing Office at
http://www.access.gpo.gov
(select “Access to Gov’t. Information Products”, then scroll to “Quick Links”)

• California Bureau of Narcotics Enforcement at
http://www.stopdrugs.org

• International Narcotics Control Board at
http://www.incb.org

• United Nations Drug Control Program at
http://www.undcp.org

• National Association of Boards of Pharmacy at
http://www.nabp.net

Appendix J

Chemical Diversion Notices*

Combination Ephedrine and Pseudoephedrine Drug Products Are Being Seized at Clandestine Methamphetamine Laboratories

The Drug Enforcement Administration (DEA), the California Bureau of Narcotic Enforcement (BNE) and other state/local law enforcement authorities throughout the United States have noted an alarming trend involving illicit methamphetamine production. Shortly after DEA placed domestic record keeping and reporting requirements on ephedrine tablets, effective April 16, 1994, there was a dramatic change in the choice of precursors used by clandestine laboratory operators. Criminals are now using bulk ephedrine and pseudoephedrine and ephedrine and pseudoephedrine drug products to clandestinely manufacture methamphetamine.

This notification is being sent to all those who either manufacture, import, export, or distribute combination ephedrine and/or pseudoephedrine products. All persons engaged in these activities should be aware of the following information:

1. Pseudoephedrine and ephedrine are List I chemicals under federal law.
2. Pseudoephedrine and combination ephedrine drug products are List I chemicals, as defined by 21 U.S.C. § 802.
3. Anyone who manufactures, imports, exports or distributes a listed chemical is considered a “regulated person” by definition of 21 U.S.C. § 802.
4. “Any person who possesses or distributes a listed chemical knowing, or having reasonable cause to believe that the listed chemical will be used to manufacture a controlled substance, except as authorized by this title, shall be fined in accordance with Title 18, or imprisoned not more than 20 years, or both,” 21 U.S.C. § 841 (d) (2).

Records, reports and proof of identity for customers are required for all regulated transactions in combination ephedrine and pseudoephedrine products. Distributors of these products should familiarize themselves with federal and state requirements. Law enforcement authorities are asking for your voluntary cooperation to reduce this diversion. Suspicious orders should be reported to your local DEA office immediately.

*The Office of Diversion Control sends chemical diversion notices to industry to provide information on emerging patterns of diversion. DEA distributes these notices to individual corporations and to associations that represent the affected industries.

PHENYLPROPANOLAMINE DRUG PRODUCTS ARE BEING SEIZED AT CLANDESTINE AMPHETAMINE LABORATORIES

The Drug Enforcement Administration (DEA), the California Bureau of Narcotic Enforcement (BNE), and other state/local law enforcement authorities throughout the United States have noted an alarming trend involving illicit amphetamine production. In March 1995 DEA sent a similar notice regarding pseudoephedrine diversion. Subsequent to that notice a number of domestic and international enforcement actions reduced the availability of pseudoephedrine. In response to that shortage of illicit precursors, traffickers are using phenylpropanolamine (PPA) to clandestinely manufacture amphetamine. This notification is being sent to all those who either manufacture, import, export or distribute PPA. All persons engaged in these activities should be aware of the following information:

PPA is a List I Chemical under Federal law.

Phenylpropanolamine drug products are List I Chemicals, as defined by 21 U.S.C. § 802. Anyone who manufactures, imports, exports or distributes a listed chemical is considered a "regulated person" by definition of 21 U.S.C. § 802.

"Any person who possesses or distributes a listed chemical knowing, or having reasonable cause to believe that the listed chemical will be used to manufacture a controlled substance except, as authorized by this title, shall be fined in accordance with Title 18, or imprisoned not more than 10 years, or both." ....Title 21 U.S.C. § 841 (d)(2).

The current exemption from certain record keeping and reporting requirements for phenylpropanolamine drug products does not reduce the risk of criminal liability. Law enforcement authorities are asking for your voluntary cooperation to reduce this diversion. Report all suspicious orders to your nearest DEA office immediately.

TO DISTRIBUTORS OF LIST I CHEMICALS:

Acceptable Documentation of DEA Registration Status
March 1999

It has come to our attention that some persons are circumventing the registration system and fraudulently obtaining List I chemicals. These persons are forging registration applications (DEA Form 510), back dating them to before the applicable exemption deadlines (11/13/95 for non-exempt all List I chemicals; 7/12/97 for combination ephedrine drug products; and 12/03/97 for pseudoephedrine and phenylpropanolamine drug products). Copies of these falsified 510's are then presented to suppliers in order to obtain List I chemicals. Suppliers know that persons who submitted applications prior to the applicable deadline can continue to conduct business until the applications are acted upon by DEA. Many suppliers have been accepting these 510 copies as indication that the presenting companies are in compliance with the statute and regulations. This practice does not represent valid compliance with verification requirements.

DEA is alerting suppliers that copies of DEA Form 510 are not acceptable identification for sales of List I chemicals. Suppliers should only accept a registration certificate or, for companies with pending applications that were submitted prior to the applicable deadlines, a letter from DEA showing the firm's DEA chemical application control number and a statement authorizing the firm to continue business until the registration application is approved by DEA. If a supplier receives documentation that is questionable, contact the nearest DEA Diversion Group by telephone. Such proposed transactions should be considered suspicious and reportable.

DEA provides quarterly registration status updates to the Department of Commerce for the National Technical Information Systems (NTIS). Any interested party can purchase this information directly from NTIS at 1-800-553-6847.

TO MANUFACTURERS AND DISTRIBUTORS OF LIST I AND LIST II CHEMICALS:

Theft of List I and II Chemicals on the Rise

A large tablet manufacturer recently reported the theft of 4.8 million pseudoephedrine tablets. Not only did this loss cost the company thousands of dollars, it resulted in the diversion of product sufficient to produce four hundred pounds of methamphetamine.

Unfortunately, this problem has become increasingly common. Manufacturers and distributors of List I and II chemicals should be aware that theft of controlled chemicals is on the increase.

The Methamphetamine Control Act (MCA) has made it more difficult to obtain precursor chemicals through legitimate channels, and unsuspecting companies have found themselves the target of employee and outsider thefts of listed chemicals. The most common stolen chemicals are pseudoephedrine and ephedrine, but DEA has received reports of theft for most of the chemicals on the List I schedule.

You can help prevent this expensive problem before it begins. If you have not already done so, consider adopting policies to reduce risk, such as:

– random physical inventory checks,
– anti-theft security measures,
– and employee background investigations.

Working together, we can keep controlled chemicals out of the hands of criminals.

November 1998

IODINE IS BEING USED TO MAKE METHAMPHETAMINE

The Drug Enforcement Administration (DEA), and numerous state/local law enforcement authorities throughout the United States have noted an alarming trend involving illicit methamphetamine production. Methamphetamine (AKA speed, crank or meth) is fast becoming a major drug problem in the United States. We are asking all businesses engaged in the sale of iodine products to be aware of the use of iodine by clandestine methamphetamine laboratory operators.

Criminal elements routinely use iodine in the illicit production of methamphetamine. DEA is aware that these criminals are searching for sources of supply for iodine. In some instances, distributors have reported the theft of iodine from chemical storage facilities.

This notice is being provided to:

– Make you aware that iodine became a federally regulated List II chemical on 10/3/96 under the Comprehensive Methamphetamine Control Act of 1996.

– Make you aware that iodine is being used to clandestinely produce methamphetamine.

– Encourage all distributors of iodine to know their customer before they unwittingly become a supplier to a clandestine methamphetamine laboratory, and report all suspicious activity to your closest law enforcement agency, and

– Advise all distributors of iodine that it is unlawful for any person to knowingly or intentionally manufacture, distribute, export, or import any equipment, chemical, product, or material which may be used to manufacture a controlled substance or listed chemical or knowing, intending, or having reasonable cause to believe that it will be used to manufacture a controlled substance or listed chemical in violation of the Controlled Substances Act... 21 U.S.C. § 843 (a)(7). Persons who violate 21 U.S.C. § 843 (a)(7) may be subject to criminal or civil penalties.

Law enforcement authorities are asking for your cooperation in this matter.

July 22, 1999

METHYL SULFONE (AKA MSM, DMS, DIMETHYL SULFONE OR DMSO2) IS BEING USED AS A CUTTING AGENT FOR METHAMPHETAMINE

The Drug Enforcement Administration (DEA), and numerous state/local law enforcement authorities throughout the United States have noted an alarming trend involving illicit methamphetamine production. Methamphetamine (AKA speed, crank or meth) is a major drug problem in the United States. We are asking all businesses engaged in the sale of methyl sulfone products to be aware of the use of methyl sulfone by methamphetamine distributors. MSM is normally used as an animal feed supplement.

Criminal elements routinely use methyl sulfone as a cutting agent or diluent in the production of methamphetamine. DEA is aware that these criminals are searching for sources of supply for methyl sulfone. In some instances, distributors have reported the theft of methyl sulfone from chemical storage facilities.

This notice is being provided to:

1. Make you aware that methyl sulfone is being used as a cutting agent or diluent in the production of methamphetamine.
2. Encourage all distributors of methyl sulfone to know their customer before they unwittingly become a supplier to methamphetamine manufacturers or distributors, and to report all suspicious activity to your local DEA office or closest law enforcement agency.
3. Advise all distributors of methyl sulfone that it is unlawful for any person to knowingly or intentionally manufacture, distribute, export, or import any equipment, chemical, product, or material which may be used to manufacture a controlled substance or listed chemical knowing, intending, or having reasonable cause to believe that it will be used to manufacture a controlled substance or listed chemical in violation of the Controlled Substances Act — 21 U.S.C. § 843 (a)(7). Persons who violate 21 U.S.C. § 843 (a)(7) may be subject to criminal or civil penalties.

Law enforcement authorities are asking for your cooperation in this matter.

July 30, 1999

SUSPICIOUS PURCHASE INDICATORS FOR SALES OF ANHYDROUS AMMONIA

Efforts by the Drug Enforcement Administration (DEA), numerous state/local law enforcement authorities and an industry anti-meth task force organized by the Agricultural Retailers Association and the Alliance of State-Agri Business Associations have been focused on raising the awareness of the theft of ANHYDROUS AMMONIA from retailer facilities and farms for the illicit production of methamphetamine. In response, several states have enacted laws against the theft of anhydrous ammonia.

As increasing levels of deterrents are put into effect, there may be increased attempts to purchase anhydrous ammonia directly from businesses engaged in the sale of agricultural supplies. The following is a list of key suspicious purchase information that should alert you to such a purchase - it is being provided to make you aware that anhydrous ammonia is being used to clandestinely produce methamphetamine.

Customer cannot answer or is evasive about agricultural use questions

Customer insists on taking possession rather than having it delivered

Customer insists on using cash, money order or cashiers check

Customer is a stranger and unfamiliar to area or your business

Customer provides suspicious business or credit information

If a customer fits any of these criteria, wait until the person has left your business, write down an accurate description of the person(s), vehicle, license number, etc., and contact the DEA or local law enforcement authorities immediately.

July 1999

Thefts of Regulated Drug Products That Contain Ephedrine or Pseudoephedrine Are Increasing

Pseudoephedrine and ephedrine are highly coveted by drug traffickers who use these chemicals to manufacture methamphetamine for the illicit market. The Drug Enforcement Administration (DEA) is receiving reports of thefts and unexplained losses of large quantities of these substances from distributors.

To prevent thefts, DEA strongly suggests that List I chemical handlers follow these guidelines:

- Maintain a system to control your inventory and monitor for unexplained losses or disappearances
- Prevent employee theft by requiring employee background checks and drug testing. In addition, DEA registrants must follow the guidance of U.S. Code of Federal Regulations 21 § 1309.72 in regard to employing persons with drug felony convictions and possibly limiting their access to List I chemicals.
- Improve physical security with anti-theft measures such as maintaining stock in a segregated area, limiting employee access to stock, and operating surveillance cameras.

In the event of theft, DEA reminds List I chemical handlers of the regulatory requirement:

- A regulated chemical handler must immediately report thefts and losses to the nearest DEA office and should also notify state/local law enforcement and regulatory agencies. A written report must be submitted to DEA within 15 days of discovery of the theft or loss. (CFR 21 § 1310.05)

To prevent recurring thefts, DEA recommends the following:

- List I chemical handlers should treat an individual theft or significant loss seriously and should monitor occurrences so that patterns do not remain undetected.
- When improving security after a theft, extend security improvements to all locations which store or distribute listed drug products.
- The repeated loss of small quantities of listed chemicals over a period of time may indicate a significant aggregate problem that must be reported to DEA, even though the individual quantity of each occurrence does not appear to be significant.

In an environment in which traffickers are aggressively seeking pseudoephedrine and ephedrine, List I chemical handlers should view unexplained losses as likely thefts. DEA registrants must provide effective controls and procedures to guard against theft and diversion of these List I chemicals. A chemical handler who experiences thefts and/or losses must take special action. Continuing to rely on a system that has been violated is **not** providing effective controls.

November 2000

Appendix K

List of Legal Requirements Applying to Regulated Persons / Regulated Transactions

Requirement	List I 21 CFR § 1310.02 (a)	List II 21 CFR § 1310.02 (b)
Proof of Identity 21 U.S.C. § 830 (a)(3); 21 CFR § 1310.07 It is the duty of each regulated person who engages in a regulated transaction to positively identify each party to the transaction.	√	√
Records 21 U.S.C. § 830 (a); 21 CFR Part 1310 Each regulated person who engages in a regulated transaction shall keep a readily retrievable record of the transaction.	√	√
Reporting Suspicious Orders 21 U.S.C. § 830 (b)(1); § 842 (a)(11); 21 CFR § 1310.05 (a)(1) Each regulated person shall report any suspicious regulated transaction. Additional information can be found in the report of the Suspicious Orders Task Force.	√	√
Registration 21 U.S.C. § 822; 21 CFR Part 1309 Every person who manufactures or distributes any List I chemical shall obtain a registration.	√	
Import/Export Notification 21 U.S.C. § 971 (a); 21 CFR Part 1313 Each regulated person who imports or exports a listed chemical in greater than threshold quantities shall notify DEA not later than 15 days before the transaction (unless DEA waives the 15 day requirement).	√	√
Authorization of International Transaction 21 U.S.C. §971 (d); 21 CFR §1313.32 and §1300.02 (15) A broker or trader located in the United States and participating in a threshold shipment of a listed chemical across an international border, other than a U.S. border, must notify DEA no later than 15 days prior to shipment.	√	√
Security 21 U.S.C. § 823 (h); 21 CFR § 1309.71-73 Registrants must maintain effective controls to prevent diversion.	√	
Mail Order Reports 21 U.S.C. § 830 (b)(3) Each regulated person who engages in a transaction with a nonregulated person which involves drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine and who uses the Postal Service or any private carrier shall report monthly.	√	
Other Recurring Reports 21 U.S.C. § 830; 21 CFR § 1310.05-06 Every registered manufacturer shall submit manufacturing, inventory, and use data on an annual basis. For tableting and encapsulating machines, each domestic sale and each importation shall be reported.	√	

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Plain Language

The Drug Enforcement Administration makes every effort to write clearly. If you have suggestions as to how to improve the clarity of this manual, call or write to:

Liaison and Policy Section
Office of Diversion Control
Drug Enforcement Administration
Washington, D.C. 20537
Telephone (202) 307-7297

Small Business Regulatory Enforcement Fairness Act

This publication is intended to provide guidance and information on the requirements of the Controlled Substances Act and its implementing regulations. If you require additional clarification or assistance, or wish to comment on any matter regarding DEA's requirements or regulatory activities, please contact your local DEA office Diversion Group. Every effort will be made to respond promptly to your inquiry.

Furthermore, please be aware that the Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the enforcement actions of the DEA Diversion Program, call 1-888-REG-FAIR (1-888-734-3247).